| (51) International Patent Classification⁴ : A61N 5/02 | A1 | (11) International Publication Number: WO 89/11311 |
| | | (43) International Publication Date: 30 November 1989 (30.11.89) |

(21) International Application Number: PCT/US89/02154

(22) International Filing Date: 18 May 1989 (18.05.89)

(30) Priority data:
195,584   18 May 1988 (18.05.88)   US

(71) Applicant: KASEVICH ASSOCIATES, INC. [US/US]; 175V New Boston Street, Woburn, MA 01888 (US).

(72) Inventors: KASEVICH, Raymond, S. ; 680 Wellesley Street, Weston, MA 02193 (US). McQUEENEY, James, F. ; 22 Birch Road, Natick, MA 01760 (US). CROO-KER, Ronald, H. ; 116 Franklin Street, Stoneham, MA 02180 (US).

(74) Agent: WALPERT, Gary, A.; Hale and Dorr, 60 State Street, Boston, MA 02109 (US).

(81) Designated States: AT (European patent), AU, BE (European patent), BR, CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent).

Published
With international search report.

(54) Title: MICROWAVE BALLOON ANGIOPLASTY
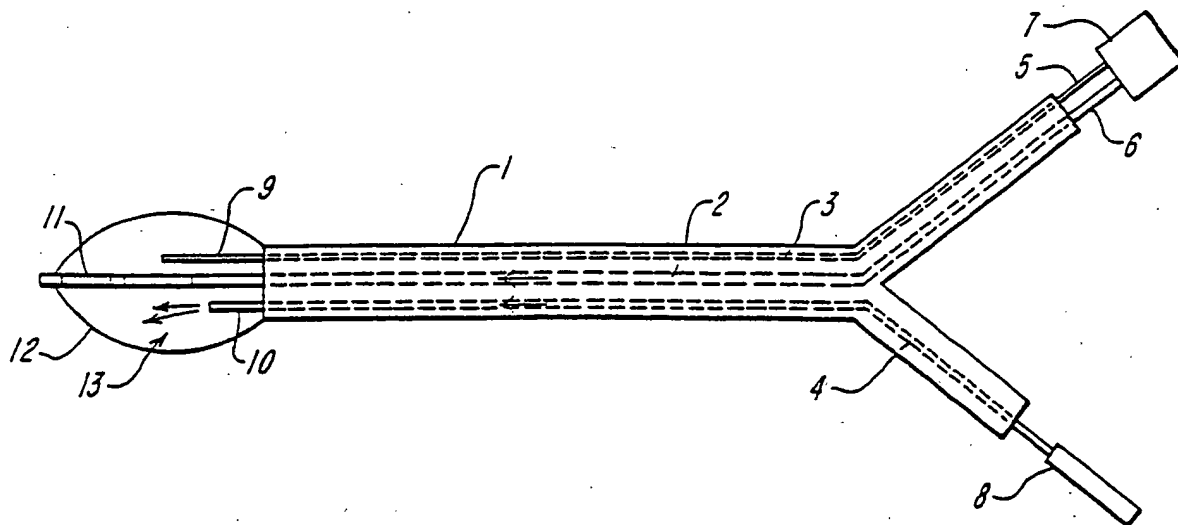
(57) Abstract

A microwave catheter system used for heating arterial plaque and including a catheter member (1) adapted for positioning in the artery and an inflatable balloon (12) supported at the distal end of the catheter member (1). Microwave energy is coupled by means of a transmission line (2) to an antenna (11). An optic fiber (3) extends through the catheter member and may be used for temperature sensing or other purposes. A channel (4) is provided through the catheter member for coupling a fluid to the bal-

-1-

MICROWAVE BALLOON ANGIOPLASTY

RELATED APPLICATIONS

The present application is a continuation-in-part of application Serial No. 100,465, filed on September 24, 1987, which in turn is a divisional application of U.S. Serial No. 834,199, filed February 27, 1986, and now granted as U.S. Patent No. 4,700,716.

BACKGROUND OF THE INVENTION

I.   Field of the Invention

The present invention relates in general to microwave balloon angioplasty, and pertains more particularly to a microwave or radio frequency catheter system for the heating of plaque in arteries or blood vessels. Also described herein are improvements pertaining to features of the microwave catheter system, including improved antenna constructions and associated fiber optics.

II.   Background Discussion

Balloon angioplasty is now a relatively well-accepted alternative to bypass surgery for high-grade obstructive atherosclerotic lesions of the peripheral, renal and coronary vessels. In this regard, U.S. Patent No. 4,643,186, entitled "Percutaneous Transluminal Microwave Catheter Angioplasty," by Rosen et al., describes a coaxial cable and antenna for microwave heating of artery plaque. This system suffers from several shortcomings which make it difficult, if not impossible, to develop a well controlled volume of heat within the plaque material. Also, for small arteries where catheter diameter and flexibility are critical, the system described by Rosen et al. does not allow for sufficient transmission of microwave power to the plaque for

-3-

catheter member adapted for positioning in the artery,
and adapted to support at the distal end thereof an
inflatable balloon. A microwave signal generator is
disposed at the proximal end of the catheter member.
5   A transmission line means couples from the signal
generator through the catheter member and includes at
its distal end an antenna means. Optic fiber means
extends through the catheter member between proximal
and distal ends thereof, and has one end thereof
10   disposed in the balloon in juxtaposition with the
antenna means. Channel means extend through the
catheter member between proximal and distal ends
thereof for coupling a fluid to the balloon for
inflation thereof.
15   In accordance with further features of the
present invention, the channel means has an entrance
port to the balloon and further includes a pressurized
fluid source for introducing fluid to the balloon
under pressure. The signal generator is excited for a
20   predetermined period of time upon injection of the
inflating fluid. The optic fiber means has a sensor
at the distal end within the balloon to measure
temperature in or at the surface of the balloon, and
in one embodiment, a pair of sensors are employed for
25   measuring temperature at separate locations within the
balloon. The antenna means may comprise a collinear
array antenna. This antenna may be disposed inside of
the balloon, or may be disposed within the skin
forming the balloon. The collinear array antenna may
30   be formed in a spiral to provide full balloon
circumferential coverage, or may, alternatively, be
formed in a helix.. In still a further embodiment of
the invention, the collinear array antenna may include
separate antenna sections in combination with a power
35   divider for intercoupling the transmission line to the

used for exciting these filaments. The filaments may
be disposed either inside the balloon or within the
skin of the balloon. In another embodiment of the
invention, the antenna means is comprised of a

5   plurality of spacedly disposed antenna wires arranged
about the balloon near the inside surface thereof, and
commonly coupled to the transmission line.

     In accordance with still a further feature of the
present invention, there is provided a triaxial

10   fiberoptic/RF cable that is in the form of a fiber
core having multiply deposited layers on the core,
including a conductive layer defining a conductor, a
dielectric coating defining an insulating layer and an
outer conductive layer defining an outer conductor.

15   In accordance with still a further embodiment of
the present invention, the balloon itself is
constructed of a compliant material that is either
loaded with a lossy material or coated with a flexible
material sufficiently loaded with lossy particles to

20   allow for absorption of microwave energy in the
balloon directly. Also, the fluid within the balloon
may be of a type having lossy particles in suspension.
The lossy material used may include ferrite or
graphite materials.

25   IV. Brief Description of the Drawings

     Numerous other objects and advantages of the
invention should now become apparent upon a reading of
the following detailed description, taken in
conjunction with the following drawings, in which:

30   FIG. 1 is a diagram of one embodiment of the
present invention, employing a microwave balloon
catheter with a fiberoptic temperature sensor;

     FIG. 2 is a cross-sectional view at the balloon
end of the apparatus;

FIG. 18 illustrates the triaxial fiberoptic/RF cable as in accordance with the present invention adapted to transmit RF energy to a ferrite sleeve;

FIG. 19 is a further view of the embodiment of
5   FIG. 18 showing further details;

FIG. 20 is a cross-sectional view of the antenna of the antenna construction of the present invention showing, in solid lines, a cross-section of one-half of the far field antenna array pattern, each of the
10   three antenna elements, and in dotted lines the near field heating pattern resulting from the superposition of the electromagnetic energy pattern generated by the three antenna elements;

FIG. 21 is a cross-sectional view of the antenna
15   of FIG. 1 along the lines 21-21;

FIG. 22 is a cross-sectional view of the antenna of FIG. 20 along the lines 22-22;

FIG. 23 is a cross-sectional view of the antenna of FIG. 20 along the lines 23-23;
20   FIG. 24 is a cross-sectional view of the antenna of FIG. 20 along the lines 24-24;

FIG. 25 is an illustration of an insulated dipole in an ambient medium used to depict the algebraic parameters needed for calculating the optimum
25   transformation of parameters;

FIG. 26 is a plot of frequency versus power ratio in decibels for the antenna of the invention;

FIG. 27 is a side view of an optional embodiment of the invention employing a lossy sleeve;
30   FIG. 28 is a cross-sectional view of an alternate embodiment of the outermost end of the antenna construction;

FIG. 29 is an enlarged fragmentary view of FIG. 28; and

-9-

melting may be the result of interaction with the
water molecules' vibration energy levels, whereas
microwave energy absorption in plaque may be the
result of interaction with the water molecules' dipole
5   moment or rotation energy levels.

In accordance with the present invention for
successful delivery of microwave energy to the plaque,
a highly flexible miniature transmission line is used,
that can transmit sufficient radio frequency or
10   microwave power to the load (plaque). This
transmission line is to be kink-free, because of the
requirement of relatively small turning radii.

In accordance with the present invention, the
antenna system is to be designed to deliver microwave
15   energy to a specific layer of plaque without heating
wall tissue during pressure application by the
balloon. The liquid that inflates the balloon
preferably does not absorb any substantial microwave
energy. It is instead preferred that the energy be
20   concentrated at the plaque rather than in the liquid
itself that causes the balloon's expansion.

In connection with certain fabrication techniques
for the highly flexible miniature transmission line,
reference is made to description set forth hereinafter
25   relating to FIGS. 20-30.

In accordance with the present invention, there
are now described a number of techniques for providing
control of the quantity of microwave energy that is
coupled to coronary vessel plaque without heating
30   vessel tissue. A collinear antenna array is provided
inside the balloon or between two balloon surfaces
(balloon inside a balloon). In accordance with one
embodiment of the invention, a printed microstrip
circuit radiator or antenna pattern is configured in

-11-

FIG. 14 shows the antenna A extending through the balloon B and having at its tip T a concentric layer of ferrite material that may have a Curie temperature in the 400°C-500°C range. Microwave energy is rapidly

5   absorbed in the ferrite when this material is at a current maximum of the antenna. The primary function of this hot tip (when the ferrite is at the far end of the antenna) is to melt plaque (ablation). This is used for those cases where the artery is fully blocked

10 by plaque, and it would therefore be necessary to remove some plaque in order to insert the balloon. In FIG. 14, note the plaque volume at V. Once some plaque has been removed, the balloon may be inflated and the microwave angioplasty carried out.

15   As indicated previously, FIG. 27 herein teaches the use of a lossy sleeve 80 for focused heating. An alternate embodiment is to employ two ferrite sleeves F1 and F2, as illustrated in FIG. 14, some distance apart along the antenna axis but outside of and

20 essentially in front of the balloon. In this regard, the arrow A1 in FIG. 14 illustrates the direction of insertion of the antenna structure.

As indicated previously, FIG. 14 shows a two-ferrite geometry. The ferrites F1 and F2 heat through

25 the plaque (occluded artery) using microwave frequency F1. To withdraw the antenna back through the plaque and avoid sticking, the ferrite F2 is tuned to a frequency F2. It remains hot to allow the antenna to be withdrawn prior to inserting the balloon and using

30 the antenna in its normal temperature plaque welding mode. Also, this ferrite, hot tip antenna may be completely removed from the catheter in a different antenna design employed for low temperature operation.

Reference is now made to one embodiment of the

35 present invention illustrated in FIGS. 1 and 2 herein.

-13-

energy absorption within the sleeve volume. Further
embodiments of the invention cover this feature, such
as will be illustrated and described in further detail
herein in FIGS. 18 and 19.

5   Reference is now made to one embodiment of the
present invention illustrated in FIGS. 1 and 2. This
embodiment illustrates the microwave balloon catheter
1 with a fiberoptic temperature sensor. A cross-
section schematic of the balloon end is illustrated in

10   FIG. 2. The balloon 12, it is noted, is secured to
the distal end of the catheter member 1. The catheter
member 1 has three lumens for carrying, respectively,
the microwave coaxial transmission line 2, the
fiberoptic cable 3, and the channel 4, which is for

15   the coupling of the electrically low loss fluid 13 to
the balloon 12 for inflation purposes.

FIG. 1 also illustrates, in the system, a
microwave signal generator 7 that includes fiberoptic
temperature processing circuitry. The generator 7, it

20   is noted, couples with the cable 6 and also the
fiberoptic cable 5. These cables are continuations of
the aforementioned cables 2 and 3.

FIG. 1 also illustrates the fluid source 8, which
may comprise a pump for pressurizing the fluid,

25   connected to the channel 4. As indicated previously,
the fluid 13 pumped from the source 8 is preferably a
low loss tangent liquid or gas that is adapted to
minimize microwave or radio frequency energy
absorption.

30   The balloon 12 is inflated by means of the liquid
13 injected into it under pressure at the entrance
port 10. FIGS. 1 and 2 also illustrate a microwave
antenna 11 that supplies electromagnetic energy to the
liquid 13 for, say, a period of 30 seconds. The

35   liquid 13 is low loss so that the energy from the

-15-

length. The balloon length and length of the plaque
deposit should coincide with the antenna length, as
measured along the balloon axis. Alternatively, the
collinear array may be positioned along the axis of

5   the balloon and inside the balloon, as depicted
previously in FIG. 1.

A reference is now made to FIGS. 3-6 for further
embodiments of the antenna construction. FIG. 3
illustrates the collinear array antenna 65 coupled

10   from the coaxial transmission line 2. The antenna 65
is provided in a spiral or helical configuration. In
this embodiment of the invention, it is noted that the
antenna is disposed substantially exclusively inside
the balloon. However, in the alternate embodiment of

15   FIG. 4, it is noted that the spiral or helical
configuration of the collinear array antenna is
embedded in the balloon skin.

Reference is now made to FIG. 5 for still a
further embodiment of the present invention. This

20   embodiment employs two separate collinear array
antennae 68A and 68B embedded in opposite sections of
the balloon skin. These antennae are fed from the
coaxial line 2 by means of a power tee or power
splitter, illustrated at 69 in FIG. 5.

25   Reference is now made to FIG. 6 for a further
embodiment of the present invention employing three
separate collinear array antennae 70A, 70B and 70C.
In this embodiment, each of these antennae is provided
inside the balloon skin, as illustrated. Each of

30   these antennae may couple to its own separate coaxial
microwave transmission line. For this purpose, the
catheter member, such as member 1, illustrated in FIG.
1, may be provided with means for accepting each of
these separate transmission lines. In all embodiments

35   of FIGS. 2-6, a fluid 13 is contained in the balloon

-17-

of the spiral radiator. The overall antenna structure
of FIG. 9 may be comprised of a cylindrical core 82.
This core 82 may be of a rubberlike material, and may
be hollow, so as to accept an optical fiber. The

5   surface of the core 82 may be coated with a thin film
of highly conductive metal to provide a ground plane,
as indicated at 83 in FIG. 9. Next, a thin dielectric
coating or film is provided over the entire ground
plane surface. This is illustrated at 84 in FIG. 9.

10 The dielectric coating may be, for example, titanium
dioxide. A conductive antenna pattern is printed, as
illustrated at 85 in FIG. 9, over the dielectric film
surface. The pattern 85 may be provided in a
continuous spiral patch, as illustrated in FIG. 9, or,

15 alternatively, a wraparound radiator may be provided
as illustrated at 87 in FIG. 10.

In the embodiment of FIG. 9, the coaxial
transmission line that feeds microwave or radio
frequency energy to the printed radiator pattern may

20 be connected at one end of the radiator. The
cylindrical geometry is well suited for the
application of balloon angioplasty. However, a simple
version for heating plaque may employ a flat antenna
geometry as illustrated in FIG. 8. In FIG. 10 the

25 ground plane may be curved to match the balloon
curvature lengthwise or remain straight and parallel
to the balloon axis.

Reference is now made to FIG. 11 for still
another embodiment of the present invention in the

30 form of a guide wire antenna system. The guide wire
essentially provides some stiffness to the catheter
and makes it easier to guide the catheter along the
artery channel. The guide wire itself may be employed
to form the center conductor of a feed coaxial

35 transmission line. In this regard, in FIG. 11, note

relatively closely coupled to the elements 97. The
elements 97 in turn radiate microwave energy into the
plaque.

Reference is now made to FIG. 13 for still a
5   further embodiment of the present invention. FIG. 13
illustrates the balloon 100 as connected to a group of
thin wire filaments 104 that are disposed at or near
the inner balloon surface. This grouping of filaments
or wires provides a substantially expanded center
10   conductor for radiation directly into the plaque. In
the embodiment of FIG. 13, the filaments 104 may be
disposed in a fanned-out arrangement about
substantially the full circumference of the balloon.

The conventional balloon construction employed in
15   balloon angioplasty is normally manufactured using a
clear, low microwave loss plastic material. However,
in accordance with the present invention, there is now
proposed a technique of heating plastic with microwave
energy when the balloon surface is in intimate contact
20   with the plaque. This technique of the present
invention is characterized by a balloon loaded with a
lossy ferrite or graphite material, such as a ferrite
or graphite powder, that permits the balloon material
to absorb microwave energy and therefore heat up.
25   Alternatively, a similar lossy coating may be employed
on the balloon surface to absorb microwave energy.
The energy is provided by a microwave antenna located
inside the balloon. The coated (or both coated and
loaded) balloon serves two important functions. Heat
30   may be directly applied to the surface of the plaque
without the microwaves depending on the plaque
material to have sufficient electrical loss (loss
tangent) for heat-up, and the balloon may act as an
attenuator of microwave energy to control the amount
35   of microwave energy radiated directly into the plaque.

-21-

have an optical capability. This optical capability
could be used for several purposes, i.e., visual
observations, temperature sensing, lasing, etc.

The basic triaxial applicator is illustrated in
5   FIG. 18 and is comprised of a fiberoptic cable 110,
which is the heart of the system. For the particular
application to microwave balloon angioplasty, the
fiberoptic cable is used for temperature sensing
purposes. A conductive coating, illustrated in FIG.
10   18 by the coating 112, is applied to the fiberoptic
cable. This coating becomes the microwave carrying
portion of the microwave/fiberoptic system.

A fiberoptic coating 114 is then applied to the
conductive coating. The dielectric layer 114 is of
15   proper dielectric value and thickness to make the
cable a preferred 50 ohm transmission line. Another
conductive coating 116 is applied to the dielectric
layer to form the outer conductive shield of the
cable. Reference is also now made to the cross-
20   sectional view of FIG. 19 that furthermore shows the
system as employed with a ferrite sleeve 120. The
antenna system, including in particular the inner
conductor 112 at its tip 113, may accommodate the
ferrite sleeve 120. This device converts microwave
25   energy to thermal heat in the ferrite sleeve. The
fiber core may be used for the purpose of temperature
sensing in association with a feedback system for
control of the temperature of the ferrite sleeve. It
may also find other applications in medicine, such as
30   for cauterizing. The embodiment disclosed in FIG. 19,
in particular, is used to melt or heat plaque in
arteries.

Reference is now made to FIGS. 20-24 for an
illustration of a microwave collinear array antenna in
35   the form of an applicator 10 for uniform heating of a

-23-

shown in FIG. 21 from the above-cited reference, the
effect of such resistance is to significantly change
the radiation pattern of the antenna and therefore, in
the present application, its heating pattern for
hyperthermia. The collinear array applicator 10 of
5   the present invention is therefore provided with the
appropriate value of resistance about one-quarter
—   wavelength from the end of the distal section. By
changing the applied frequency, or the location of the
resistor, the distribution of heat around the
10   applicator may therefore be changed or "steered" in
many directions.
        At the proximal end of the antenna array 10, a
coaxial impedance matching transformer is provided, in
the form of a dielectric cylinder 26 concentric with
15   and external to the outer conductor 16. The
dielectric cylinder 26 is covered with a metallic
cylinder 27, which is electrically shorted to outer
conductor 16 at proximal end A. A dielectric outer
envelope 14 extends over the full length of cylinder
20   27 and distal section B-E. The transformer minimizes
the reflected power within the feed transmission line
and also prevents leakage of antenna currents along
the outside of the array applicator 10. By judicious
selection of operating parameters, both functions
25   (minimizing reflected power and leakage prevention)
occur at approximately the same operating frequency.
The operating parameters of the coaxial impedance
matching transformer are based on the theoretical
equations developed by R.W.P. King, ("The
30   Electromagnetic Field of an Insulated Antenna in a
Conducting or Dielectric Medium," R.W.P. King et al.,
IEEE Transactions on Microwave Theory and Techniques,
Vol. MIT-31, No. 7, July 1983).

-25-

elements at the distal end of the array (and
decreasing the spacing between elements), a higher
sectional antenna gain is achieved, as compared to the
more proximal section B-C, which will have a lower

5   gain because it is a single $(3\lambda/2)$ element.
More specifically, the square of the electric field
for the half-wavelength [1], full wavelength linear
[2] and 3/2 wavelength [3] antennae in free space,
shown below, provides an indication of the radiated

10   power distribution for the collinear array in lossy
material (J.D. Jackson, "Classical Electrodynamics,"
J. Wiley, 1975, 2nd ed., pp. 402-403):

$$(1) \quad \text{For } \frac{\lambda}{2} \text{ Antenna: } E^2 \alpha \; \frac{\cos^2 (\overline{2} \cos\theta)}{\sin^2}$$

$$(2) \quad \text{For } \lambda \text{ Antenna: } E^2 \alpha \; \frac{4 \cos^4 (\frac{\pi}{2} \cos\theta)}{\sin^2 \theta}$$

$$(3) \quad \text{For } \frac{3\lambda}{2} \text{ Antenna: } E^2 \alpha \; \frac{\cos^2 (3\pi/2 \cos\theta)}{\sin^2\theta}$$

wherein θ is measured from the longitudinal axis of
the antenna.

The full wave antenna, distribution (C-E), can be
considered as resulting from the coherent

20   superposition of the fields of two collinearly
adjacent half-wave antennae patterns B_2 and B_3 excited
in phase; the power intensity at $\theta = \pi/2$ is 4 times
that of half-wave length antenna. Thus, the extreme
distal section (C-E) of two series connected half wave

25   antennae radiates 6 dB more power per solid angle than
the three half wave length section (B-C). Based on
geometric reasoning, the total power radiated by the

-27-

the proper transformer operation using the criterion
that the complex propagation constant k_L of the
transformer dielectric is the same as the k_L of the
distal section. A uniform silver ink coating is then
5   applied over the polyacrylamide material to form a
second conductive layer 27. This second conductive
layer 27 is present only over the length of the
proximal section. It is applied in a manner which
creates a short circuit to the silver ink outer
10 conductor 16 at proximal end A but leaves an open
circuit between it and the outer conductor 16 at point
B. The outer PTF coating 14 is then applied over the
proximal section A-B or continued from the distal
section.

15   This coating 14 permits the probe to operate
within wide limits of variations of temperature,
tissue dielectric constant and electrical
conductivity. A 10 mil thick coating of PTF permits
the array to maintain a constant heating pattern
20 (ignoring the effects of heat loss or gain by
conduction or convection) for a change in the
dielectric constant of tissue from 30 to 80 which may
occur during heat application.

Within the dielectric coating 14, fiberoptic
25 thermometry sensors 24 may be embedded. A sensor,
such as that produced by the Luxtron Corporation ("16-
Channel Fiberoptic Thermometry System with Multisensor
Arrays for Thermal Mapping," Wickersheim et al.) may
be appropriately modified for application to the array
30 10. Several linear phosphor sensors 24 about 0.25 mm
in diameter (10 mils) may be embedded in the outer
dielectric 14. The phosphor sensors 24 utilize the
temperature dependence of the fluorescent decay time
of the phosphor to determine temperature.

-29-

The general theory of the insulated antenna
applies when the wave number of the ambient medium is
large compared to that of the insulating sheath and
the cross-section of the antenna is electrically

5   small. That is

$$|k_4/k_2|^2 \; 1; \; |k_4/k_3|^2 \; 1; \; (k_2 b)^2 \; 1; \; (k_3 c)^2 \; 1. \quad (1)$$

Subject to these conditions and with the time
dependence $e^{-i w t}$, the current in the central conductor
is

$$I(z) = I(0) \; \frac{\sin k_L(h-|z|)}{\sin k_L h}$$

10

$$I(0) = V_0^e Y_0 = V_0^e/Z_0 \quad (2a)$$

where admittance is:

$$Y_0 = -(i/2Z_c)\tan k_L h. \quad (2b)$$

For a dielectric with two layers:

15 $$k_L = k_2 \frac{\ln(c/a)+F}{\ln(c/a)+n_{24}F} \; \left[\frac{1}{2} \frac{\ln(c/a)}{\ln(b/a)+n_{23}^2\ln(c/b)} \right]^{1/2} \quad (3)$$

$$Z_c = (\omega\mu_0 k_L/2\pi k_2^2)[\ln(b/a)+n_{23}^2\ln(c/b)+n_{24}^2 F] \quad (4)$$

20 where $n_{23}^2 = k_2^2/k_3^2$, $n_{24}^2 = k_2^2/k_4^2$,

and $F = H_0^{(1)}(k_4 c)/k_4 c H_1^{(1)}(k_4 c)$;

wherein $H_0^{(1)}(k_4 c)$ and $H_1^{(1)}(k_4 c)$ are zero and
first order Hankel functions of the first kind.

These formulas can be simplified by the

30 introduction of an effective wave number K_{2e} and an

-31-

transformer must match with β_L, and $\beta_L \ d = \pi/2$ gives the
required length of the transformer. β_L is the real
part of k_L of Equation 6. The transformer length is
the length of the proximal section. Proper impedance
5   matching of the collinear antenna array is therefore.
dependent on the value of k_L. For the proper choice
of dielectric inside the transformer and length of
transformer, a high value of impedance will exist at
the input (Section B). This will effectively isolate
10   the array from the feed line, and with the proper
location of the input of the transformer from gap 5,
give a collinear array which is properly matched to
the 50 ohm feed line.

FIG. 26 shows the ratio of reflected power (P_r)
15   to transmitted power (P_t) in decibels in the coaxial
line for a 10 cm long, 3 gap, collinear array of 2
millimeter diameter made in accordance with the
invention. The frequency fo is the frequency which
yields the highest value of terminating impedance for
20   the array wherein the elements of the array are
harmonically related. For the 10 cm device in the
example, the collinear array that achieves the uniform
heating pattern consists of the elements depicted in
the distal section B-E of FIG. 20, wherein the
25   frequency is 915 megahertz. The transformer length is
about 1 centimeter with a PTF dielectric inside the
transformer, having a dielectric constant of 40.

As shown in the optional embodiment of FIG. 27, a
lossy sleeve 80 comprised of ferrite cores or beads
30   formed in the shape of a cylinder with an inner bore
may be disposed about the applicator 10 at the distal
end thereof. Preferably, the inner diameter of the
bore in sleeve 80 forms a press fit with the outer
diameter of the applicator 10 and is held in place
35   along the longitudinal length of the applicator by a

-33-

conductor 16 of the antenna array is terminated by a
radially inwardly extending ring, shown as sections
16a and 16b. A beam steering resistor 22 may be
disposed along the longitudinal axis of the antenna in
5   the path of inner conductor 20, as shown.
Alternatively, an equivalent beam steering resistor 21
may be formed as a circular ring embedded in outer
insulator 14.

The inner walls of ring sections 16a and 16b are
10 insulated from resistor 22 or (in the event resistor
22 is not present) from inner conductor 20 by
dielectric disk 62. The inner conductor is extended
radially from the longitudinal axis by disk-like
conductor member 18c which is integral with coaxial
15 conductor 18a encased in dielectric 14.

The collinear applicator array 10 may be
connected to a commercially available coaxial cable,
as shown in FIG. 30, by means of a flexible coaxial
connector adaptor 60. This type of connector will
20 eliminate the need to use expensive commercially
available SMA connectors. In addition, the size of
SMA connectors may be excessive in diameter for
certain applications, thereby creating the need for a
special connector whose diameter will conform to the
25 diameter of the collinear applicator.

As shown in FIG. 30, the adaptor comprises a
laminated metal conductive ring 40 or ferrule having
an inner diameter conforming to the outer diameter of
the outer conductor 16 of applicator 10 affixed around
30 the outer conductor. The adaptor of FIG. 30 may be
located at various positions along the transmission
line. The outer conductor 16, dielectric core 18 and
inner conductor 20 of applicator 10 are allowed to
extend longitudinally outward from the proximal end of
35 the applicator, with the core 18 extending beyond the

-35-

    1. Angiographic techniques for access to arterial or venous components (using fluoroscopy);

    2. Endoscopic techniques for access to the urethra, prostate, bladder, ureters, and renal pelvis via retrograde cannulation (using fiber optic endoscopy, i.e., cyrtoscopes);

    3. Percutaneous techniques for direct access by way of so-called antegrade nonsurgical approach through the flank or back to the renal pelvis; ureter and bladder (using CT, ultrasound, fluoroscopic or even endo-urologic equipment).

    The currently available state-of-the-art imaging equipment (particularly ultrasound and CT) allows visualization and direct puncture of masses in the neck, abdomen, pelvis, and extremities. Under ultrasonic or CT guidance, long, small diameter needles (18-23 gauge) are easily introduced through the skin and into superficial or deep lesions. In a similar manner, the applicator probe 10 could be easily introduced into these lesions through any number of widely available biopsy needles.

    The same techniques and equipment can be used for the relatively non-invasive (i.e., non-surgical) access and treatment of other anatomical sites. For example, the gastrointestinal tract, specifically, the biliary system, is routinely approached by endoscopic means (ERCP-endoscopic retrograde cannulation of the pancreas), as well as percutaneously by direct intercostal puncture and catheterization of the liver and bile ducts for diagnosis and treatment of . malignant and benign obstructions (due to hepatic, biliary, pancreatic, and lymph node diseases). Other lesions of the GI tract, such as in the stomach, are

-37-

from the generator thereof to the balloon structure.
The transformer section of the collinear array
antenna, such as illustrated in FIGS. 11 and 20, is
employed to ensure good impedance matching and no
5   antenna current leakage along the outer surface of the
outer conductor of the coax line. Various forms of
transmission line structure may be employed inside the
balloon or on the inside surface of the balloon, or
even between two balloons, one inside the other.

10   The radiating transmission line structure within
the balloon may be a simple two wire arrangement, or
may employ multiple wire combinations connected
together so that the electric field of the wires
extends into the plaque, thus avoiding the heating of
15   artery tissue. In another arrangement, a leaky coax
wire may be of various cross-sectional geometries.
They may be, for example, microstrip or strip line, as
illustrated hereinbefore.

        By varying the spacing between these conductors,
20   the number of conductors employed, and the electrical
phasing of each conductor, a specific electric field
distribution can be achieved in the plaque region. In
this regard, refer to the previously described FIG. 6
that shows antenna elements. Also refer to FIG. 13.
25   Thus, in addition to the use of wires, one can use
several collinear array antennae, as illustrated in
FIG. 6. For example, if four collinear array elements
are used, forming a square pattern, and the elements
are spaced one-half wavelength apart, current phasings
30   of 0°, 90°, 270°, and 360° or 0° will place the
resultant heating pattern in the center of the square.

        For the transmission line system illustrated in
FIG. 31 herein, the resultant heating pattern is
larger, or, in other words, the electric field extends
35   outside the square to a greater extent in comparison

-39-

flexible inside the balloon. Although the helix can
radiate in several modes, the most commonly used modes
for antenna practice are the axial and normal modes.
The axial mode provides maximum radiation along the
5   helix axis. It occurs when the helix circumference is
on the order of one wavelength. The normal mode,
which yields radiation broadside to the helix axis,
occurs when the helix diameter is small with respect
to the wavelength. Higher order radiation modes are
10   also possible. For example, when the helix dimensions
exceed those required for the axial mode, higher order
radiation modes exist. The resultant pattern is
referred to as a conical or multi-lobed pattern. It
is this mode of radiation that is insensitive to
15   structures or materials located inside the helix.
        The basic radiation patterns for free space
helices are shown in FIG. 31. The basic helix
geometry is also indicated. The pertinent design
parameters for a free space environment are:
20   D = diameter of helix (center to center)
            C = circumference
            S = spacing between turns
            a = pitch angle
            N = number of turns
25   L = axial length of helix
            d = diameter of helix
            l = length of one turn
        The helix antennae can be designed with bifilar,
quadrifilar or multifilar windings. They can be
30   designed with non-uniform diameters and tapered
diameters. Various types of tapered designs are shown
in FIG. 34. The envelope taper with either constant
pitch angle or constant spacing between turns
represents a design shape suitable for balloon
35   application. Various possible constructional and feed

-41-

dielectric sheath. The thin film process technology
application is illustrated herein in FIG. 36. FIG. 36
shows the center conductor wire 200. The wire 200 is
then coated with a dielectric material, as indicated

5 at 202. On the dielectric material there is then
evaporated or sputtered a thin metallic film forming
the outer conductor as indicated at 204 in FIG. 36.
The deposition of the outer layer may be by physical
vapor deposition or by chemical vapor deposition

10 (CVD).

The next step is to preferably wrap a metal helix
on the coax cable for improved insertion loss and
mechanical integrity. Dielectric materials may be
deposited on the cable to create the aforementioned

15 transformers.

Having now disclosed a number of embodiments of
the present invention, it should be apparent to those
skilled in the art that numerous other embodiments and
modifications thereof are contemplated as falling

20 within the scope of the present invention as defined
by the appended claims.

-43-

5.   A microwave catheter system for heating
arterial plaque as set forth in claim 4 including a
pair of sensors for measuring temperature at two
locations within the balloon.

5   6.   A microwave catheter system for heating
arterial plaque as set forth in claim 1 wherein said
antenna means comprises a collinear array antenna.

7.   A microwave catheter system for heating
arterial plaque as set forth in claim 6 wherein the
10   collinear array antenna is disposed inside the
balloon.

8.   A microwave catheter system for heating
arterial plaque as set forth in claim 6 wherein the
collinear array antenna is disposed within the skin
15   forming the balloon.

9.   A microwave catheter system for heating
arterial plaque as set forth in claim 6 wherein the
collinear array antenna is formed in a spiral to
provide full balloon circumferential coverage.

20   10. A microwave catheter system for heating
arterial plaque as set forth in claim 6 wherein the
collinear array antenna is formed in a helix to
provide full balloon circumferential coverage.

-45-

17. A microwave catheter system for heating
arterial plaque as set forth in claim 15 wherein said
radiator is of annular configuration, having an outer
radiating strip.

5   18. A microwave catheter system for heating
arterial plaque as set forth in claim 15 wherein said
radiator includes a hollow member coated with a thin
conductive film to form a ground plane, a thin
dielectric film over the ground plane, and a
10   conductive antenna pattern printed over the dielectric
film surface.

19. A microwave catheter system for heating
arterial plaque as set forth in claim 18 wherein said
antenna pattern is in a spiral form.

15   20. A microwave catheter system for heating
arterial plaque as set forth in claim 1 wherein said
transmission line means has a center conductor of
sufficient stiffness to form a guide wire.

21. A microwave catheter system for heating
20   arterial plaque as set forth in claim 20 including
impedance matching means along said center conductor
at the location where the center conductor enters and
leaves the balloon.

22. A microwave catheter system for heating
25   arterial plaque as set forth in claim 21 wherein the
transmission line means has an outer conductor except
at positions within the balloon, a tip of the center
conductor extending beyond said balloon.

29. A microwave catheter system for heating arterial plaque as set forth in claim 1 wherein said balloon is constructed of a complaint material loaded with a lossy material to allow the balloon skin to absorb microwave energy directly.

30. A microwave catheter system for heating arterial plaque as set forth in claim 1 wherein said balloon is coated with a lossy material to absorb microwave energy.

31. A microwave catheter system for heating arterial plaque as set forth in claim 29 wherein the lossy material includes ferrite or graphite material.

32. A microwave catheter system for heating arterial plaque as set forth in claim 1, wherein said antenna means comprises a helical antenna.

33. A microwave catheter system for heating arterial plaque as set forth in claim 32, wherein said helical antenna is tapered.

34. A microwave catheter system for heating arterial plaque as set forth in claim 1, wherein said antenna means comprises a segment of transmission line within said balloon.

35. A microwave catheter system for heating arterial plaque as set forth in claim 34, wherein said transmission line section within the balloon is comprised of a center conductor, a dielectric material disposed about the center conductor and a thin metallic film deposited over the dielectric material and forming an outer conductor.

40. A collinear array antenna as set forth in
claim 38 including a ferrite member arranged over said
antenna for providing enhanced heating.

41. A system for heating arterial plaque having
5   a proximal section adapted to be coupled to a source
of electromagnetic energy and a distal section for
radiating said energy, comprising: a collinear array
antenna formed by a continuous inner conductor, and a
distal end in the distal section surrounded by
10   dielectric material and an interrupted coaxial outer
conductor longitudinally extending at one end from the
proximal section to another end at the distal section
and wherein the interruptions are in the form of
circumferential gaps periodically spaced along the
15   coaxial conductor at interrelated harmonic wavelengths
to radiate a substantially uniform beam pattern of
electromagnetic energy about the periphery of the
antenna and an impedance matching means at the
proximal section.

20   42. A system for heating arterial plaque as set
forth in claim 41 in combination with a catheter
member supporting at the distal end thereof a
inflatable balloon and furthermore comprising a pair
of impedance matching means at either side of said
25   balloon.

2/10
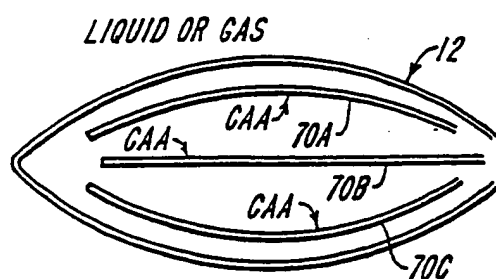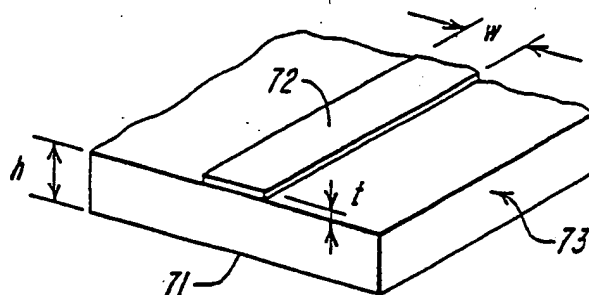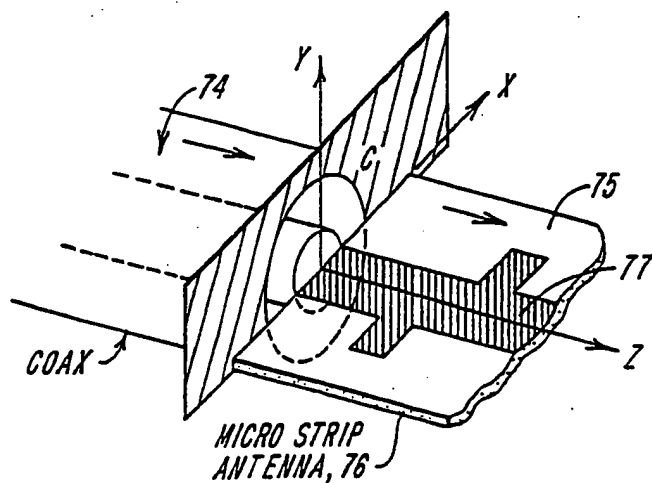
LIQUID OR GAS

FIG. 6

FIG. 7

FIG. 8

MICRO STRIP
ANTENNA, 76

FIG. 9

106

FIG. 15

108

107

FIG. 16

107

109

FIG. 17

FIG. 18

CONDUCTIVE COATING, 116
DIELECTRIC, 114
FIBEROPTIC CORE, 110
CONDUCTIVE COATING, 112

112   *120*   *113*

130

110

116   *114*

FIG. 19

4/10

$$R_2 = \sqrt{(Z+Z')^2 + r^2} = $$
$$\sqrt{R_0^2 + Z'^2 + 2R_0 Z' \cos\theta}$$

$$R_1 = \sqrt{(Z-Z')^2 + r^2} = $$
$$\sqrt{R_0^2 + Z'^2 - 2R_0 Z' \cos\theta}$$

REGION 1 = CONDUCTOR
REGION 2 = DIELECTRIC
REGION 4 = AMBIENT MEDIUM

FIG. 25

FIG. 26

FIG. 27

ELECTRIC FIELD

FIG. 31   FIG. 32

NORMAL MODE   AXIAL MODE   CONICAL MODE

$$a = \tan^{-1}\frac{S}{\pi D}$$
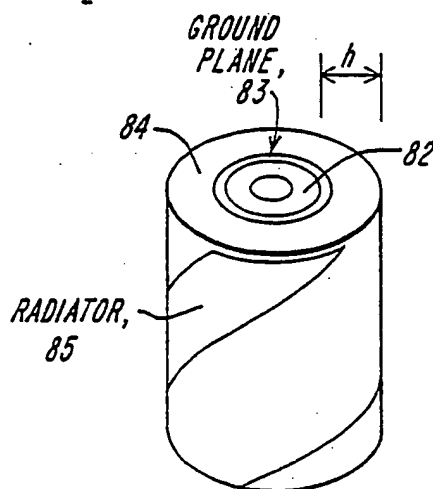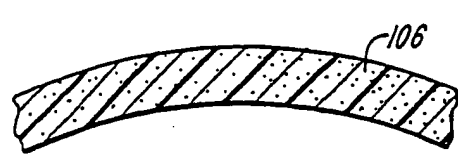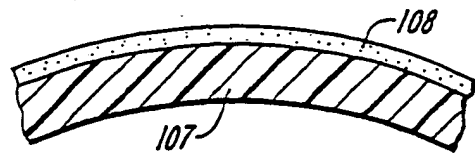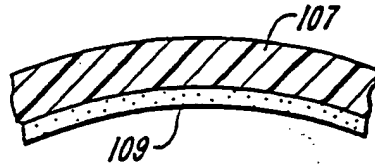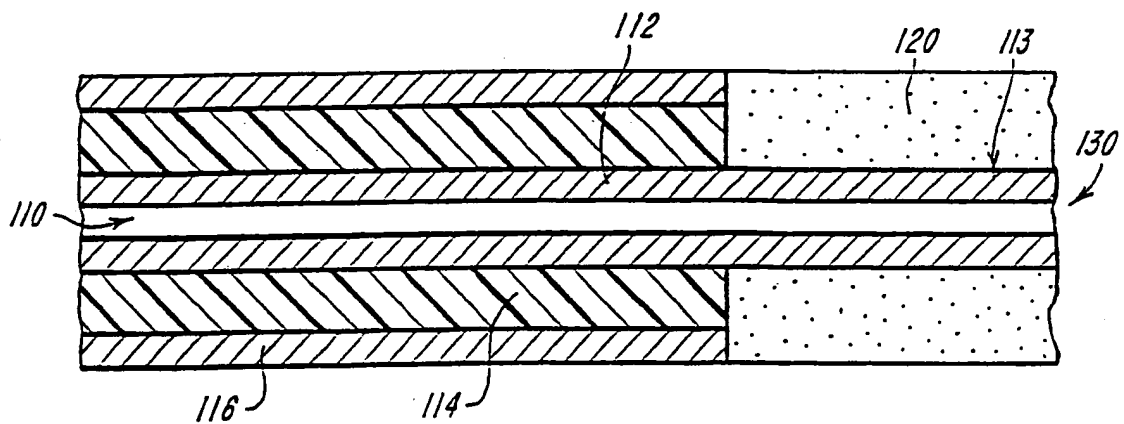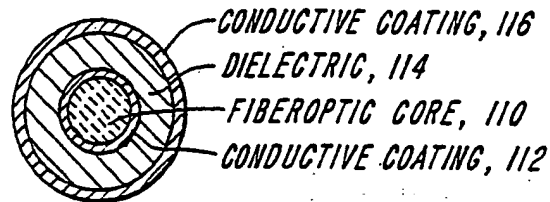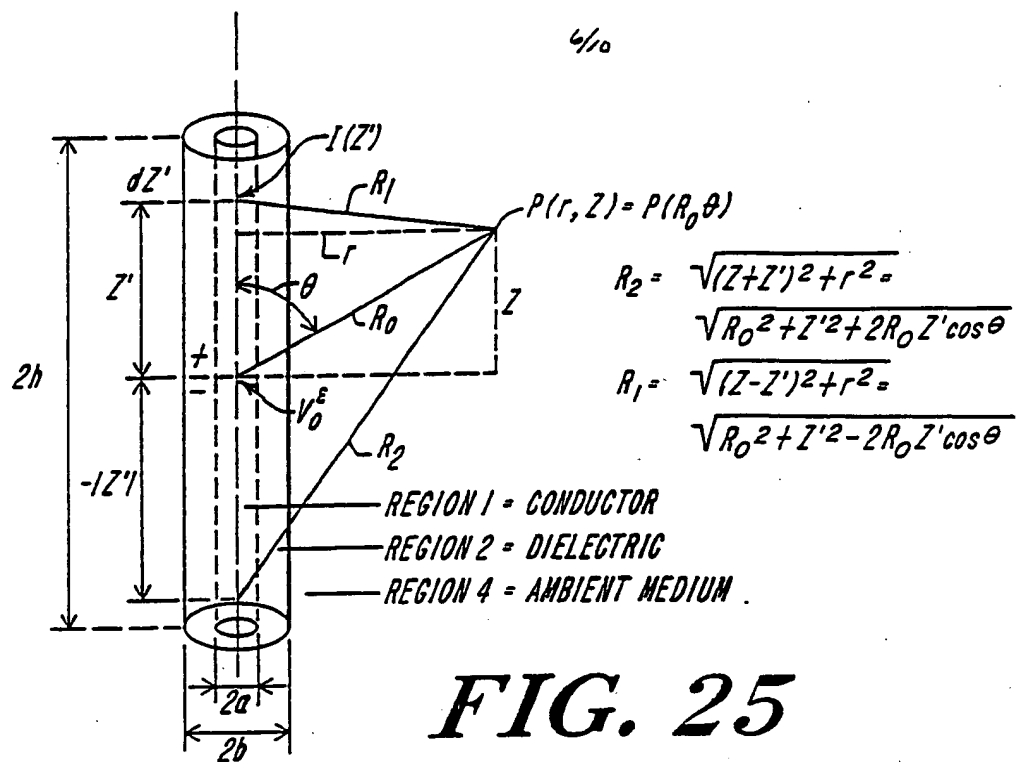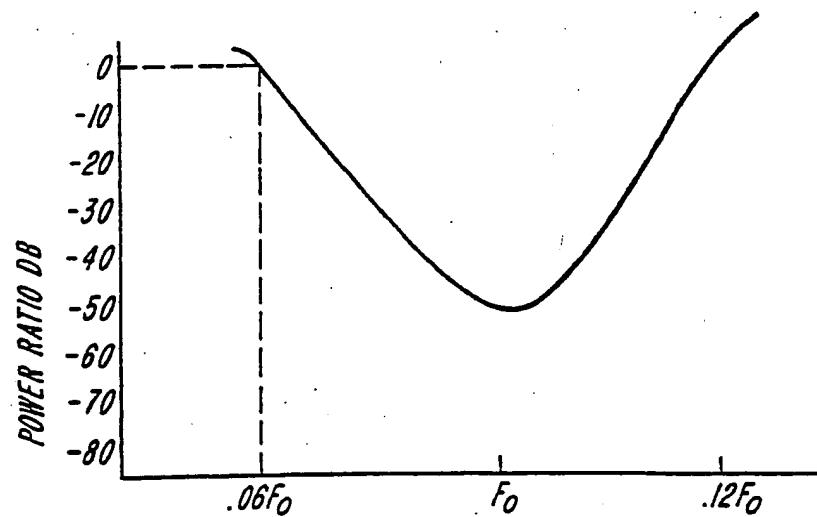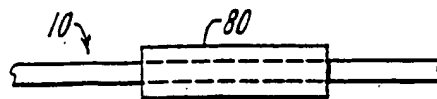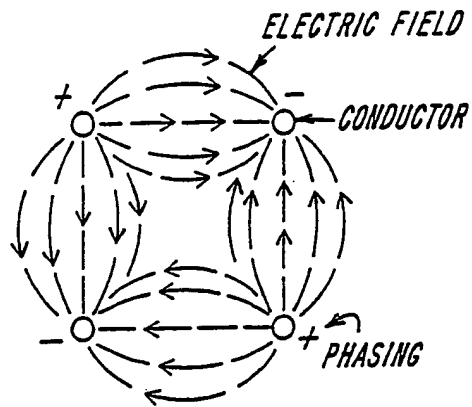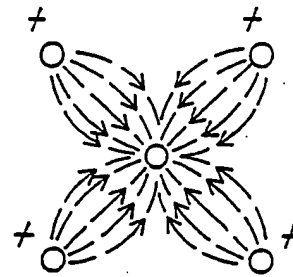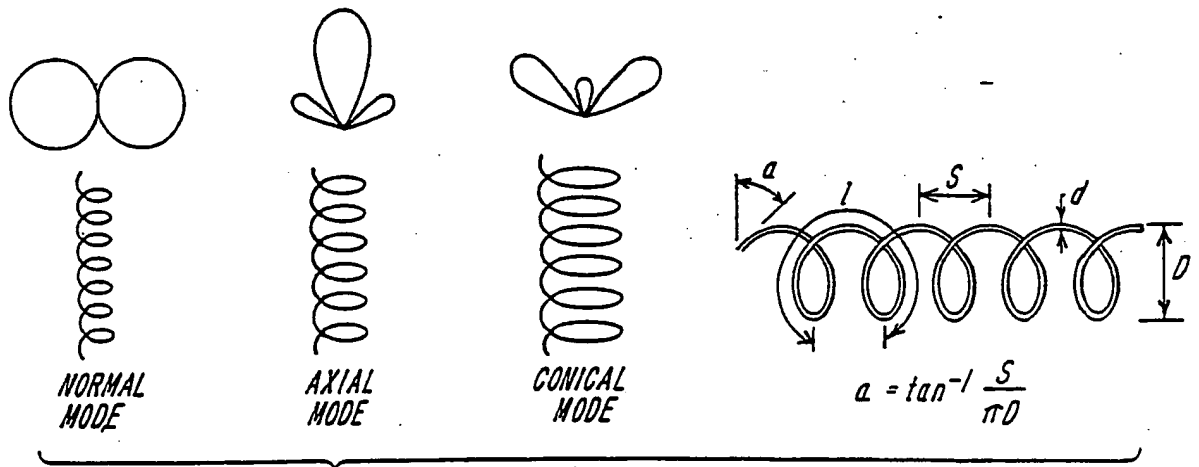
FIG. 33

10/10
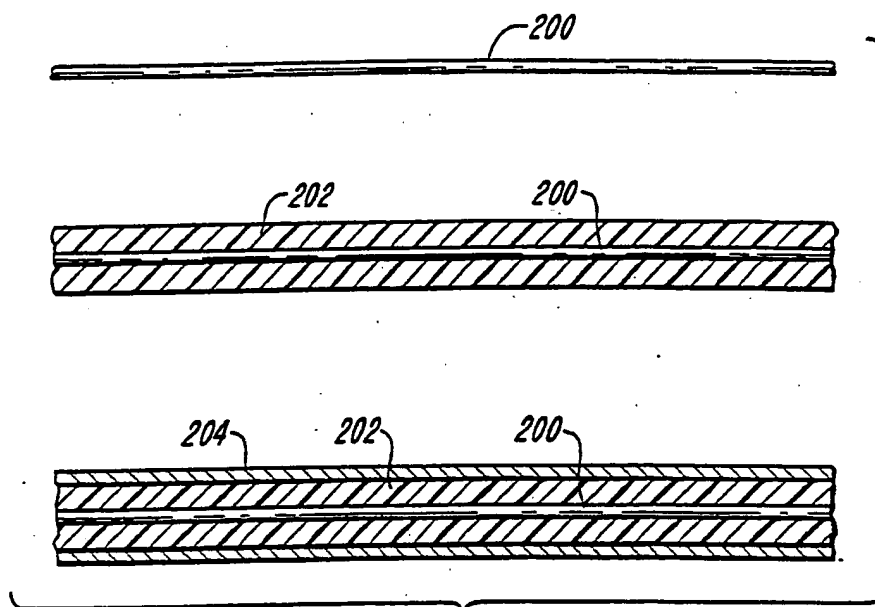
FIG. 36

III. DOCUMENTS CONSIDERED TO BE RELEVANT   (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document. with indication, where appropriate, of the relevant passages	Relevant to Claim No
A	US,A, 4,681,122 (WINTERS) 21 July 1987. see entire document.	1
X Y	GB,A, 1,188,490 (FRITZ) 15 April 1970. See entire document.	38,41 21,39, 40,42
Y	GB,A, 2,122,092 (JAMES) 11 January 1984. See entire document.	15,16, 29-31, 40
Y	EP,A, 0,105,677 (SOGAWA) 18 April 1984. See pages 1-18.	1,22, 38,41
A	DE,A, 3,516,830 (DORNER) 13 November 1986. See entire document.	23-26
Y	EP,A, 0,251,745 (KITAGAWA) 07 January 1988. See entire document.	9,10, 32,33